# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/NZ05/000023

International filing date: 18 February 2005 (18.02.2005)

Document type: Certified copy of priority document

Document details: Country/Office: NZ
Number: 531332
Filing date: 23 February 2004 (23.02.2004)

Date of receipt at the International Bureau: 14 March 2005 (14.03.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

Ministry of Economic Development
Manatū Ōhanga
Intellectual Property Office of New Zealand

PCT/NZ2005/000023

# CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 23 February 2004 with an application for Letters Patent number 531332 made by FISHER & PAYKEL HEALTHCARE LIMITED.

Dated 3 March 2005.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
NEW ZEALAND

330 High Street, Lower Hutt and 17 Toop Street, Seaview
PO Box 30687, Lower Hutt, New Zealand or DX SX 11129, Wellington
Phone: +64 4 560 1600, Fax: +64 4 560 1691, www.iponz.govt.nz

NEW ZEALAND

PATENTS ACT, 1953

# PROVISIONAL SPECIFICATION

"Breathing Assistance Apparatus"

We, **FISHER & PAYKEL HEALTHCARE LIMITED**, a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand do hereby declare this invention to be described in the following statement:

## FIELD OF INVENTION

The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides a nasal positive airway pressure device.

## SUMMARY OF THE PRIOR ART

Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's airway open, eliminating the typical OSA sleep pattern.

The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm $H_2O$. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery hose to a nose (or nose and/or mouth) mask sealingly engaged to a patient's face by means of a harness or other headgear. An exhaust port is provided in the delivery tube proximate to the mask. More sophisticated forms of positive airway pressure devices, such as bi-level devices and auto-titrating devices, are described in US Patent No. 5148802 of Respironics, Inc. and US Patent No. 5245995 of Rescare Limited, respectively.

US Patent No. 5477852 of Airways Ltd, Inc. discloses a nasal positive airway pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross-section outside the patient's nostril to a substantially oval cross-section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the sidewall of the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold

the nasal members in place and to effect treatment. The nasal device of US Patent No. 5477852 is attached to headgear that is located about a patient's head; this headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional nasal masks used for administrating CPAP treatment are also considered uncomfortable and cumbersome, also prior art nasal masks and the like are noisy (due to air leaks). These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego treatment. It is believed a substantial number of such patients could benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

As oxygen is supplied as a dry gas it is well known in the art to either heat and/or humidify gases before delivering them for breathing by a patient. In particular when delivering oxygen, or oxygen / air mixture, it has proven beneficial to humidify the gases first. In WO 01/41854 of Vapotherm, Inc. a system is disclosed that allows the delivery of humidified oxygen through a nasal cannula. This system uses a narrow bore conduit and nasal cannula with a high resistance to gas flows, thereby requiring the oxygen be of a high pressure. Air, as well as oxygen can also be passed down the conduit and nasal cannula and it too must be of a high pressure. This system allows the delivery of high flows of oxygen enriched air to the patient, but is limited in the flows achievable due to the narrow bore of the cannula resulting in high resistance gas flow and excessive velocity and noise upon exiting the cannula. Furthermore, the narrowness of the nasal cannula in this system allows easy expiration of gases between the prongs and nares and therefore does not create any positive airway pressure.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™. In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around itself and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

**SUMMARY OF THE INVENTION**

It is an object of the present invention to provide a breathing assistance apparatus which goes someway to overcoming the above mentioned disadvantages or which will at least provide the public a useful choice.

Accordingly in a first aspect the present invention consists in a breathing assistance apparatus comprising:

nasal cannula, shaped to fit within a user's nares,

a pressurised source of gases,

transportation means adapted to, in use, be in fluid communication with said source of gases and said nasal cannula and adapted to in use convey said gases to said user,

wherein said nasal cannula are adapted to deliver said humidified gases to said user, said nasal cannula including at least one prong allowing high flow delivery of said humidified gases and creates positive airway pressure in said patient's airway, the at least one prong having an end that is flared outwardly, such that in use, said flared end seals within said user's nares.

Preferably said nasal cannula has two nasal prongs.

Preferably said prongs are oval and shaped to follow the contours of human nares.

Preferably said prongs are angled toward one another to prevent dislodgement from said user's nares and assist in flow of gases into the user's nasal passages.

Preferably said prongs each have a step formed in them such that in use the sides of said prong abut the user's nasal septum so as to prevent said prongs from dislodging from said user's nares.

Preferably each of said prongs include a protrusion formed opposite said step that assists in correct orientation of said prongs within said user's nares

Preferably said nasal cannula includes a body that has a plurality of apertures that act as a bias flow outlet vent for gases exhaled by said user.

Preferably said nasal cannula is connected to said transportation means by way of a ball and socket joint.

In a second aspect the present invention consists in a breathing assistance apparatus comprising:

nasal cannula, shaped to fit within a user's nares,

a pressurised source of gases,

humidification means adapted to, in use, be in fluid communication with said source of gases and adapted to in use humidify said gases,

humidified gases transport means adapted to, in use, be in fluid communication with said humidification means and adapted to in use convey said humidified gases to said cannula,

heating means disposed within said transport means and adapted to in use heat said gases as they pass through said transport means,

wherein said nasal cannula are adapted to deliver said humidified gases to said user, said nasal cannula including at least one prong allowing high flow delivery of said humidified

gases and creates positive airway pressure in said patient's airway, the at least one prong having an end that is flared outwardly, such that in use, said flared end seals within said user's nares.

Preferably said nasal cannula has two nasal prongs.

Preferably said prongs are oval and shaped to follow the contours of human nares.

Preferably said prongs each have a step formed in them such that in use the sides of said prong abut the user's nasal septum so as to prevent said prongs from dislodging from said user's nares.

Preferably each of said prongs include a protrusion formed opposite said step that assists in correct orientation of said prongs within said user's nares

Preferably said nasal cannula includes a body that has a plurality of apertures that act as a bias flow outlet vent for gases exhaled by said user.

Preferably said nasal cannula is connected to said transportation means by way of a ball and socket joint.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the forgoing and also envisages constructions of which the following gives examples.

**BRIEF DESCRIPTION OF THE DRAWINGS**

One preferred form of the present invention will now be described with reference to the accompanying drawings.

**Figure 1** is a block diagram of a system providing humidified continuous positive airway pressure to a user as might be used in conjunction with the nasal cannula present invention.

**Figure 2** is a perspective view of the nasal cannula of the present invention.

**Figure 3** is a side view of the nasal cannula of Figure 2.

**Figure 4** is a plan view of the nasal cannula of Figure 2.

**Figure 5** is a prong end view of the nasal cannula of Figure 2

**Figure 6** is an exploded view of the nasal cannula of Figure 2.

**Figure 7** is an alternative embodiment of a nasal cannula of the present invention.

**Figure 8** is yet another embodiment of a nasal cannula of the present invention.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Whether used in a hospital environment or in a home environment, the nasal cannula of the present invention will generally have associated three main pieces of apparatus. Firstly an active humidifier that controls the temperature of a heater plate heating a body of water to achieve a desired temperature and humidity of the gases being humidified. Secondly a transport conduit from the humidifier to the patient is also required, which is preferably heated to reduce condensation, or "rain out". Thirdly a cannula designed to fit up into the nasal cavity and deliver humidified, pressurized gases. In particular, the nasal cannula of the present invention has two flared end prongs that seal within a patient's nares. The cannula prongs are shaped such that a step is created between them such that the prongs abut the user's nasal septum in use. Furthermore, the gripping action of the sides of the prongs to the user's septum in use prevents the prongs from dislodging from the user's nares.

With reference to Figure 1 a humidified Continuous Positive Airway Pressure (CPAP) system is shown in which a patient 1 is receiving humidified and pressurised gases through the nasal cannula 2 of the present invention, that are connected to a humidified gases transportation pathway or inspiratory conduit 3. It should be understood that delivery systems could also be VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) or numerous other forms of respiratory therapy. Inspiratory conduit 3 is connected to the outlet 4 of a humidification chamber 5 that contains a volume of water 6. Inspiratory conduit 3 may contain heating means or heater wires (not shown) which heat the walls of the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material and may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 that may comprise a microprocessor based controller executing computer software commands stored in associated memory.

Controller 9 receives input from sources such as user input means or dial 10 through which a user of the device may, for example, set a predetermined required value (preset value) of humidity or temperature of the gases supplied to patient 1. The controller may also receive input from other sources; for example, temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification

chamber 5. A flow of gases (for example air) is provided to the chamber through inlet 16 from a gases supply means or blower 15. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 through outlet 4. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in Figure 1.

Blower 15 is provided with variable pressure regulating means or variable speed fan 20 which draws air or other gases through blower inlet 17. The speed of variable speed fan 20 is controlled by electronic controller 18 (or alternatively the function of controller 18 could carried out by controller 9) in response to inputs from controller 9 and a user set predetermined required value (preset value) of pressure or fan speed via dial 19.

**Flared Prong Nasal Cannula**

The nasal cannula of the present invention is shown in detail in Figures 2 to 6. Referring to Figures 2 and 6, the nasal cannula 2 comprises three main components; the prong part 21, body part 22 and ball connector 23.

The prong part 21 has two nasal prongs 24, 25, each of which are substantially shaped to follow the contours of the human nares and in use are placed inside a user's nares. The prongs 24, 25 extend out from a hollow tubular body 26 that in use fits to the body part 22. Each of the prongs 24, 25 are integrally moulded with the tubular body 26 in a flexible plastics material or rubber, such as silicone, other thermoset elastomers or thermoplastic elastomers such as Kraton™. The prongs 24, 25 are substantially oval tubular members that allow for a passage of gases. In particular, as shown in Figure 5, the prongs are oval in shape and angled in the same manner as a human's nares. The prongs 24, 25 are angled toward one another (or toward the vertical axis Y) at the top 27, 28 of the prongs and away from one another at the bottom 29, 30 of the prongs. Furthermore, the ends 31, 32 of the prongs flare outwardly and preferably are formed such that the ends of the prongs are thinner in cross-section than the rest of the prongs. The flared thinner section ends 31, 32 of the prongs assist with the sealing of the prongs 24, 25 in use within the user's nares. When in use and with gases flowing through the prongs the force of the gas pressure will force the prong ends to flare outwardly more and seal against the inside of the user's nares.

The prongs 24, 25 each include a step 33, 34 formed along their lengths. Each of the steps 33, 34 are formed on the prongs 24, 25 in an opposing manner such that in use, when the prongs are within a user's nares the steps 33, 34 abut the user's nasal septum and form a ledge that prevents dislodgement of the prongs. The prongs 24, 25 also have protrusions 35, 36 formed on their outer edges that abut the sides of the user's nares (opposite to the nasal

septum). The protrusions 35, 36 assist preventing the dislodgement of the prongs, especially if the user moves his or her head. The protrusions 35, 36 also maintain the prongs within the user's nares in a correct orientation such that in use gases flow through the prongs and directly up the user's nasal passages.

The body part 22 is a tubular passageway in which the prong part 21 is connected at one end and a ball joint 37 at the other end. The ball joint 37 extends from the connector 23 and slots into a complementary shaped (half sphere) socket end 39. The body part 22 also has a number of apertures 38 formed in it, which acts as a bias flow outlet vent. Therefore, any gases exhaled by the user through their nose will exit through the apertures.

The connector 23 is preferably connected to the inspiratory conduit 3 (see Figure 1) that supplies gases flow to the cannula 2. The inspiratory conduit 3 may be moulded directly to the connector 23 or other connection mechanisms may be used, such as a friction fit formed between the connector and conduit.

Although a ball and socket joint, as described above, between the body part 22 and connector 23 is preferred other connections may be utilised, such as a flexible piece of silicone, or other appropriate connection. The connection between the cannula body and connector must be able to be flexed or rotated to allow for the inspiratory conduit 3 to be moved without causing the dislodgement of the nasal cannula 2 from the user's nares.

In the preferred form of the nasal cannula 2 of the present invention the body part 22 and connector 23 are preferably made from a hard or rigid plastics material, such as polypropylene, polycarbonate or acetyl. In other forms the body part 22 and connector 23 may be of different plastics materials to allow for increased slidability between these parts.

The prong part 21 may be supplied in various different sizes such that different sized user's may remove an existing prong part and simply attach a different sized flexible plastics prong part over the body part 22.

To provide additional comfort for the user or ensure the nasal cannula of the present invention do not fall from a user's nares, the nasal cannula may be used in combination with a headgear strap. For example, Figure 1 shows a headgear strap 40 extending from the nasal cannula 2. The ends of the headgear strap that attach to the cannula may attach to extensions (or loops) 40, 41 on the body part 22 of the cannula shown in Figure 2, or may attach about other appropriate areas of the cannula, for example, about the connector 23.

The abovementioned embodiment of the nasal cannula 2 of the present invention is preferably a wide bore pronged cannula used for high flow conditions. A further embodiment of the present invention is shown in Figure 7. In this alternative embodiment of the nasal

cannula 42 the prongs 43, 44 are preferably small bore prongs for use with lower flow conditions. The prongs 43, 44 are similarly shaped to the prongs 24, 25 detailed above, but may not seal in the same manner as the abovementioned prongs due to the smaller size of the prongs. In fact these prongs may not seal at all in use within the user's nares.

Furthermore, in this alternative embodiment the nasal cannula 42 is smaller and weights less as it is only comprised of a prong body 45 and prongs 43, 44, where the body 45 is connected to a small tube that is formed with corrugations or bellows 48 that connect to an inspiratory tube or conduit 47 (similar to the inspiratory conduit 3 described above) that receives a supply of gases.

The corrugations of bellows 48 will bend or move when a weight or force is placed on the cannula, thereby preventing dislodgement of the cannula 42 form a user's face in use. In particular, the corrugations or bellows 48 prevent in use transferral of the torque onto the cannula 42 when a user moves his or her head.

The body 45 of the cannula 42 is provided with a number of apertures 48 that allows for gases exhaled by the users to be expelled into the ambient air.

The prong body and prongs of this embodiment of the cannula of the present invention are preferably formed a flexible plastics material or rubber, such as silicone, other thermoset elastomers or thermoplastic elastomers such as Kraton™.

In yet another embodiment of the nasal cannula of the present invention the cannula may be provided with corrugated or baffled sections on the prongs as illustrated in Figure 8. The nasal cannula 49 of this embodiment is similar to that of Figure 2 but the prongs 50, 51 have a series of corrugations 52, 53 formed in them. The corrugations 52, 53 allow for movement of each of the prongs 50, 51 for a better user fit, and allow for movement of the cannula 49 without causing dislodgement of the prongs from the user's nares.

DATED THIS 23rd DAY OF February 2004
AJ PARK
PER
AGENTS FOR THE APPLICANT

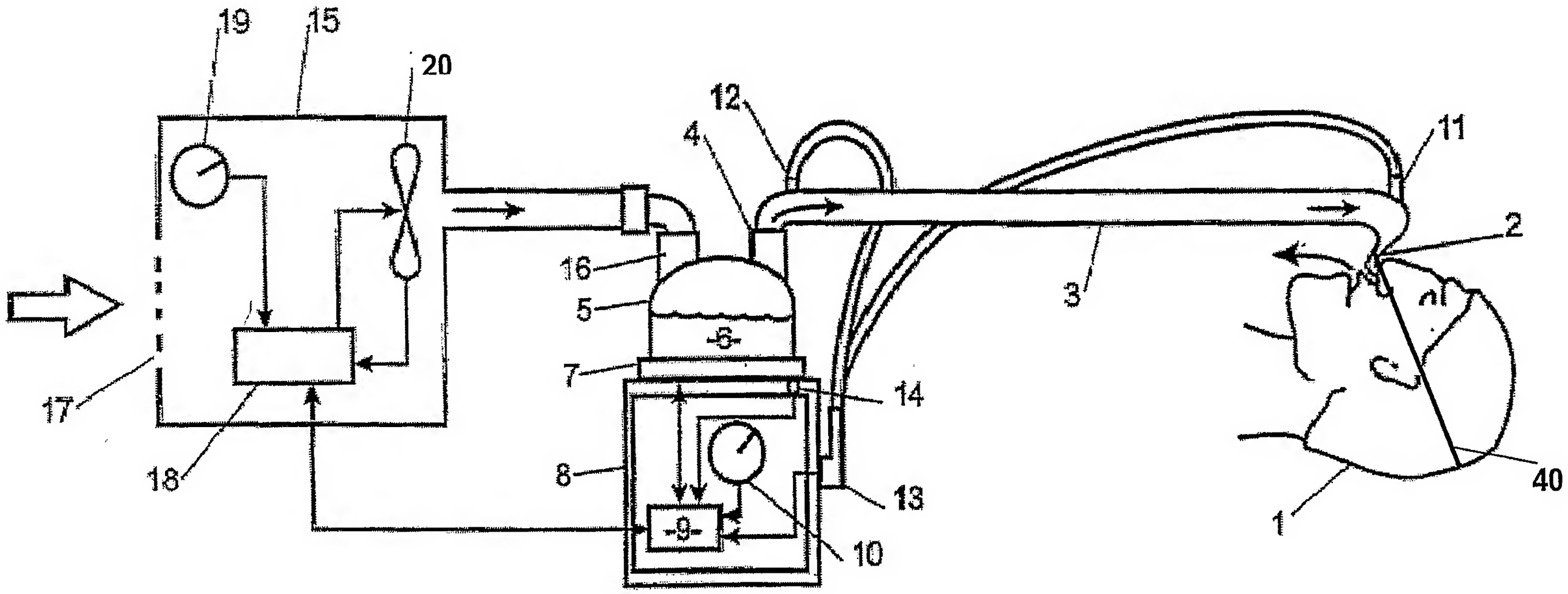


**Figure 1**

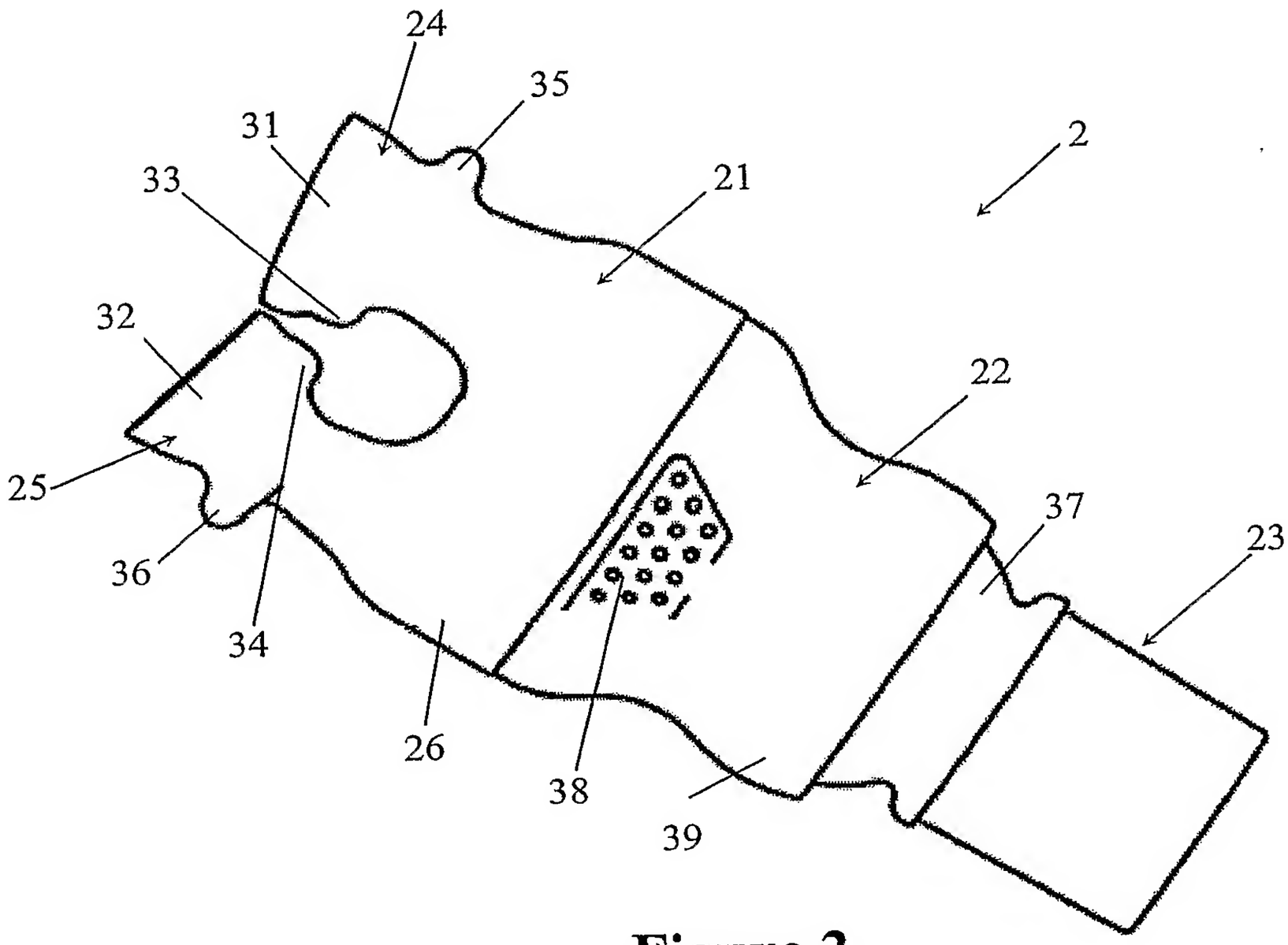


**Figure 2**

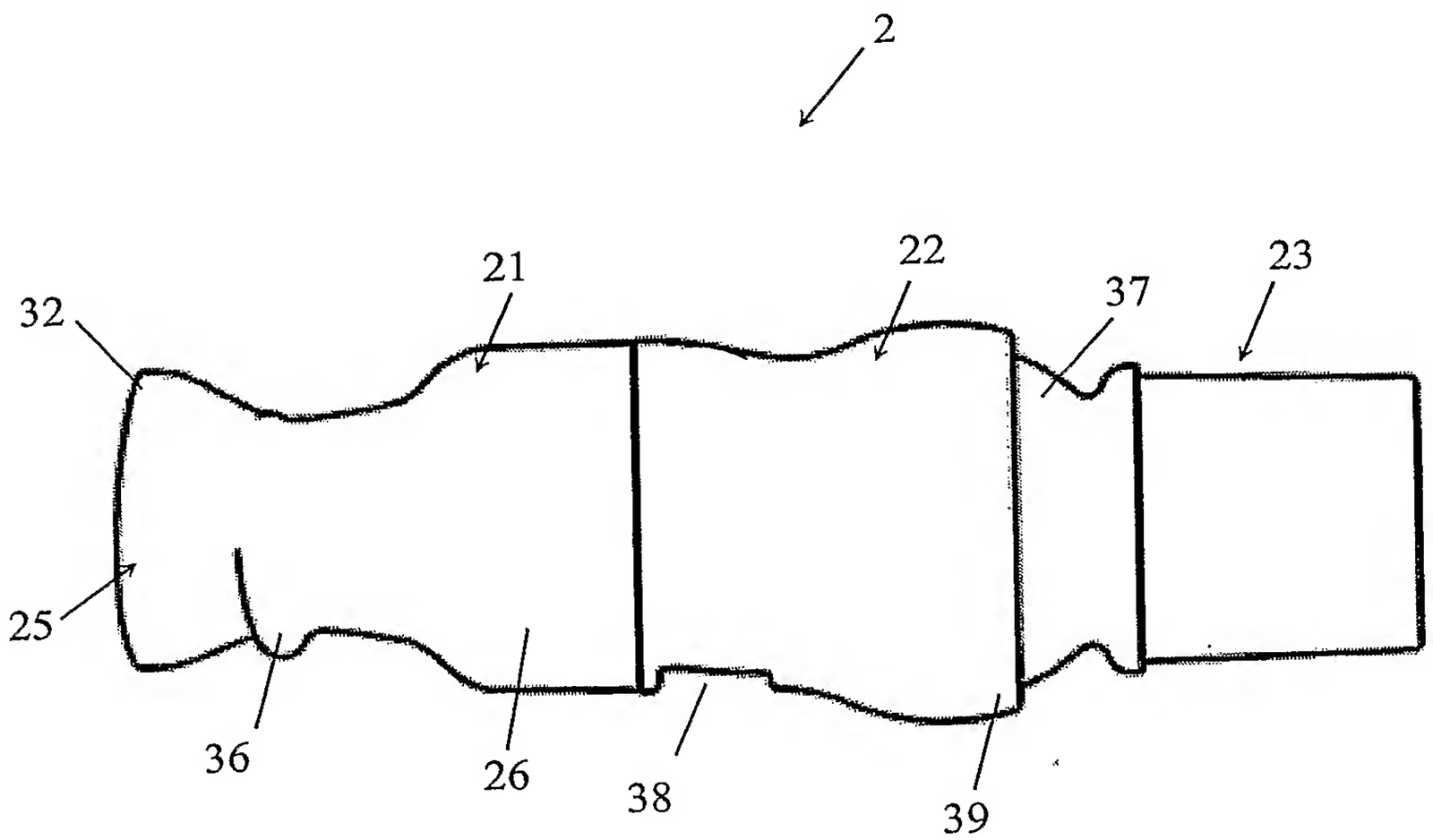


**Figure 3**

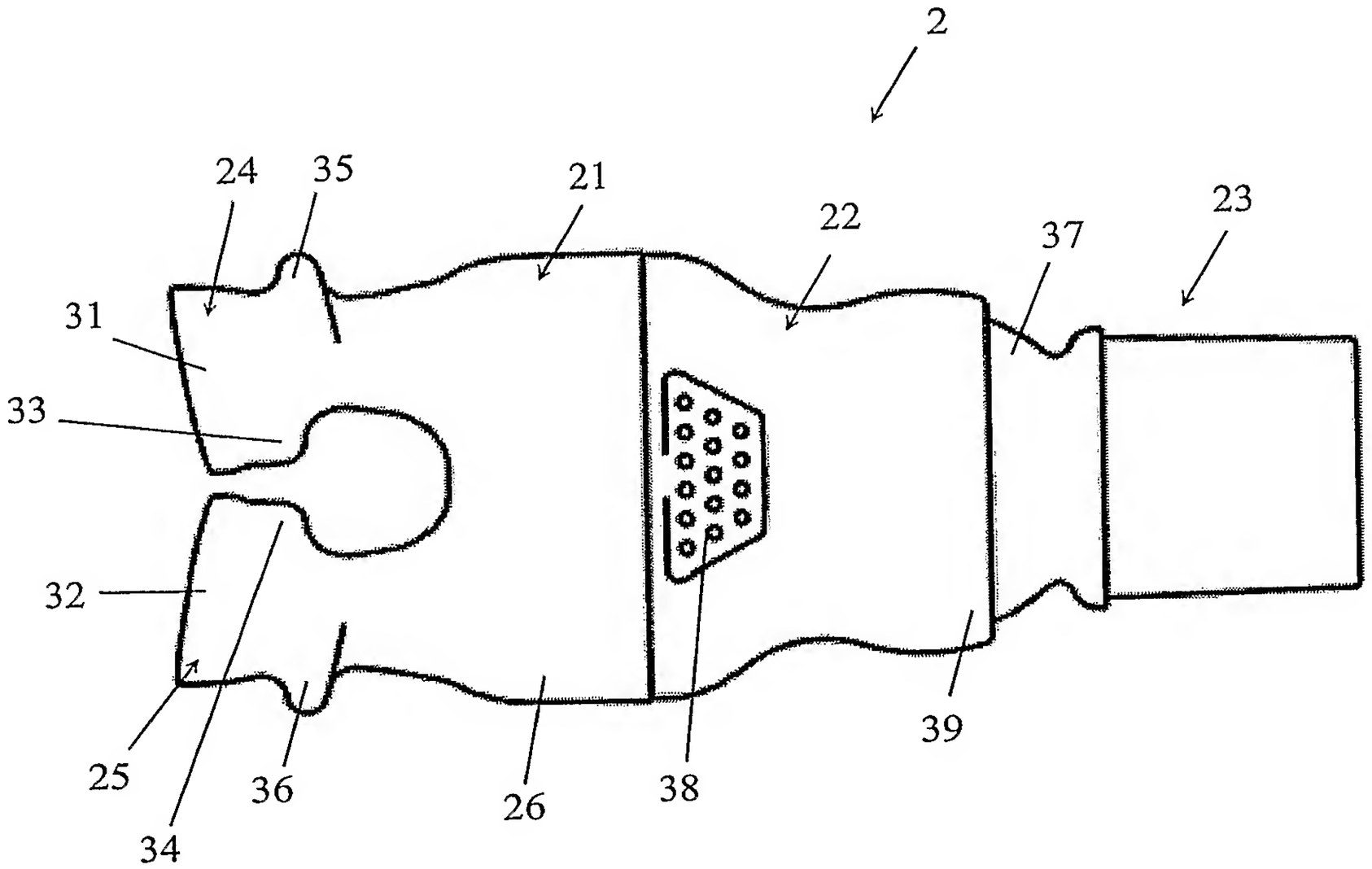


**Figure 4**

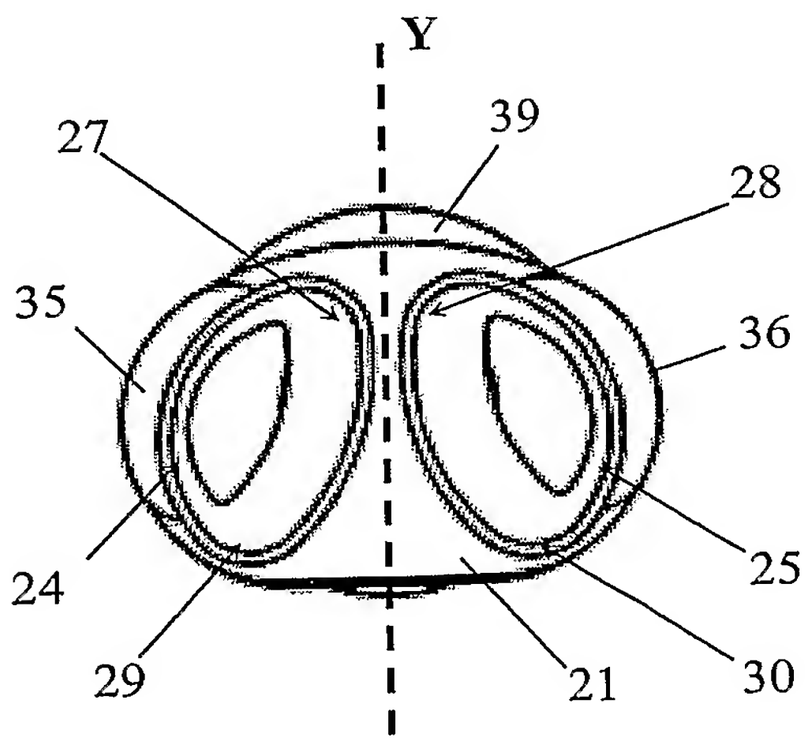


**Figure 5**

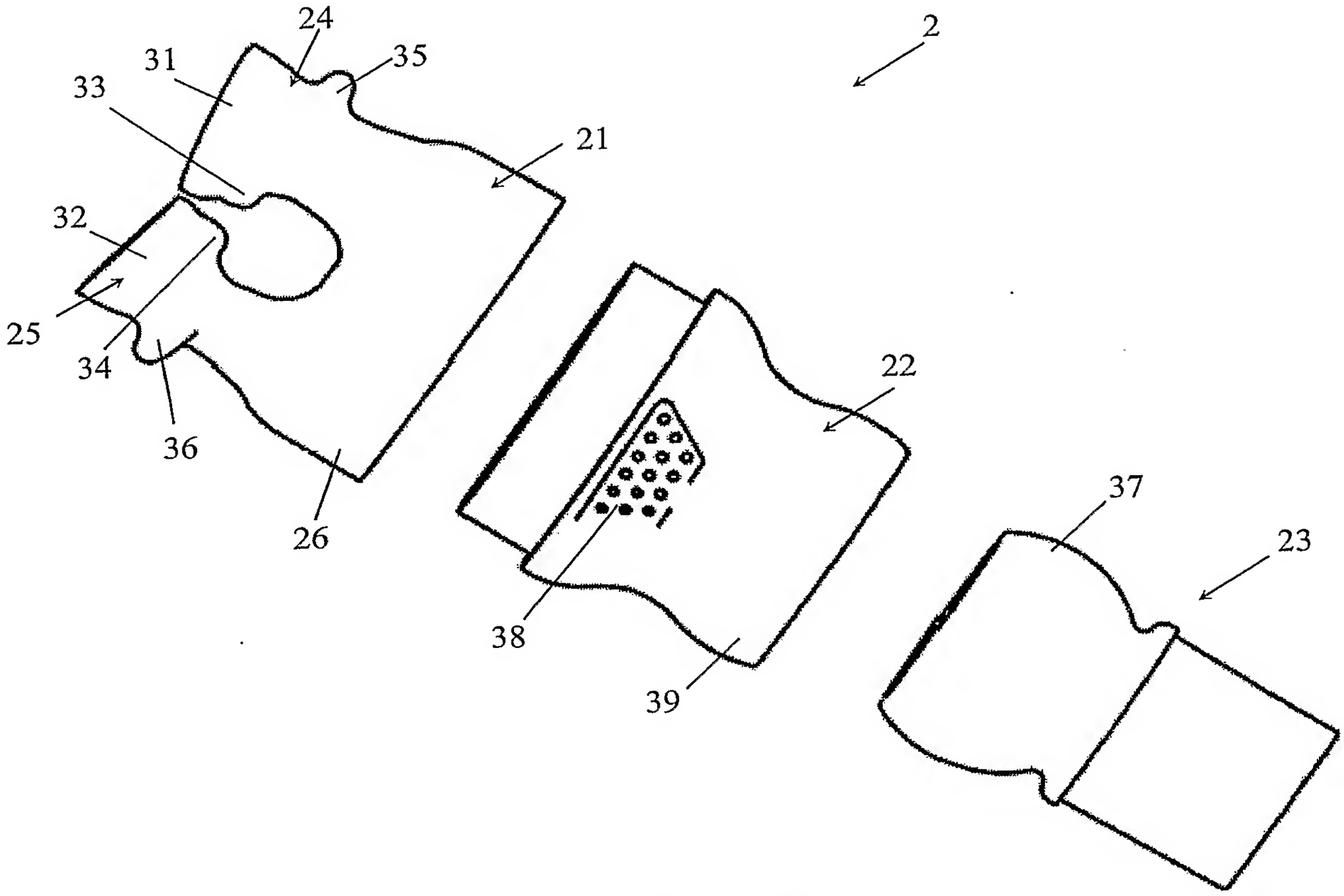


**Figure 6**

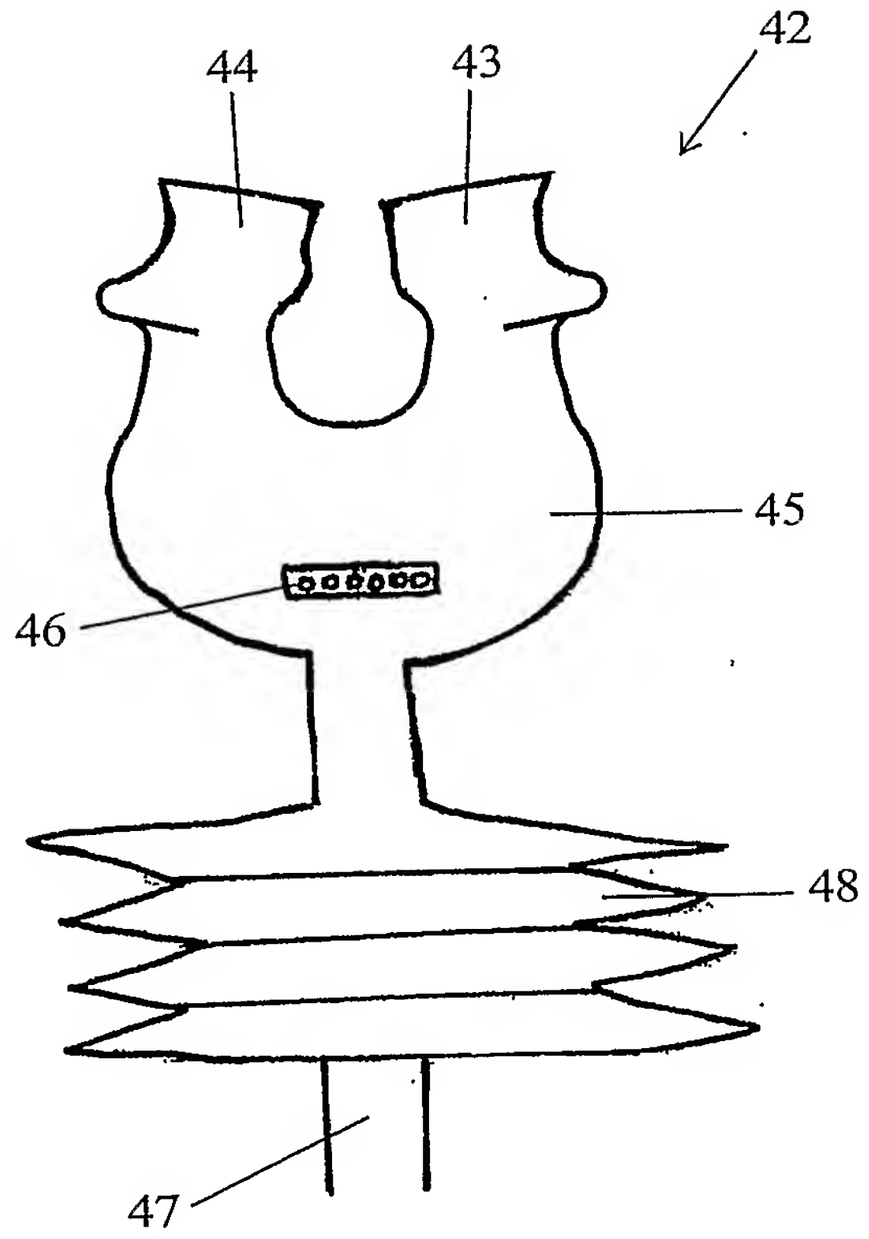


**Figure 7**

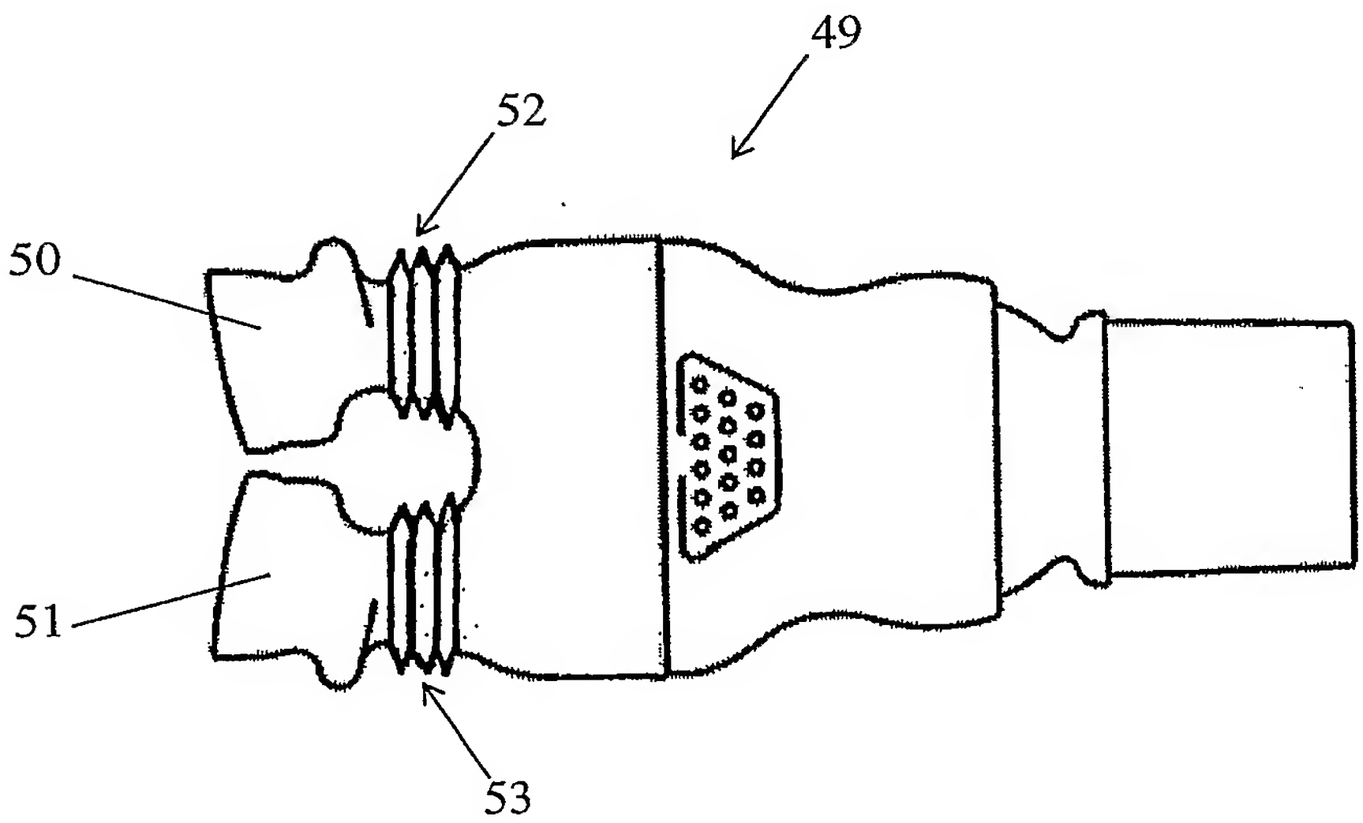


**Figure 8**